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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,599	07/07/2003	David P. Andrew	09800080-0104	7759
23552	7590	08/01/2006	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			DEBERRY, REGINA M	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/614,599

Applicant(s)

ANDREW ET AL.

Examiner

Regina M. DeBerry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). .
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 1-18, 20-37 and 39-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/03, 6/05</u> . | 6) <input type="checkbox"/> Other: _____  |

***Status of Application, Amendments and/or Claims***

The amendment filed 07 July 2003 has been entered in full. Applicant's election with traverse of Group V (claims 19 and 38 drawn to a method for determining the amount of nucleic acid in a sample) in the reply filed on 05 June 2006 is acknowledged. The traversal is on the ground(s) that the Examiner has failed to establish that the search of Groups IV and V would be unduly burdensome as they are classified in the same class. Applicant argues that a search of detecting the nucleic acid of claims 19 and 38 may also include the references relating to the detection of a polypeptide encoded by the nucleic acid.

Applicant's arguments have been fully considered but are not found persuasive. Claims IV and V are drawn to different inventions; a method for determining the amount of nucleic acid in sample and a method of determining the presence of a polypeptide in a sample. Each invention performs its function using structurally and functionally divergent material and has a different mode of operation. The distinct steps, methodology and materials require separate and distinct searches. The different methods have different subclasses. Furthermore, there are numerous situations where the polypeptide has been isolated but the nucleic acid sequence was not known. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-18, 20-37, 39-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 05 June 2006. Claims 19 and 38 are under examination.

***Information Disclosure Statement***

The information disclosure statement(s)(IDS) filed 17 November 2003 and 13 June 2005 was received and comply with the provisions of 37 CFR §§1.97 and 1.98. They have been placed in the application file and the information referred to therein has been considered as to the merits.

***Priority***

The amendment entered 07 July 2003 claims priority to provisional application 60/166,177 filed 11/17/1999. However, the BIB Data Sheet and oath/declaration state that provisional 60/166,177 was filed 11/18/1999. Appropriate correction and/or clarification is required.

A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an

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international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the

information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

### ***Sequence Rules***

In Figure 1, new S100 cytokine (SEQ ID NO:6) is listed as having 104 amino acids but in the paper copy of the sequence listing, SEQ ID NO:6 is listed as having 118 amino acids. Appropriate correction is required. Applicant must check the specification to ensure the SEQ ID Nos in the specification match the CRF and the paper copy of the sequence listing and every sequence in the specification has a SEQ ID NO: Applicant must provide a CRF and a paper copy of the Sequence Listing, as well as an amendment directing its entry into the specification. Applicant must also submit a statement that the content of the paper and computer readable copies are the same and include no new matter.

A complete response to this office action includes compliance with this sequence rule compliance. **Applicant must submit a response to this Office Action and compliance with sequence rules simultaneously.**

### ***Drawings***

1. The drawings are objected to because there are 2 "Figure 4B" drawings.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: In the Brief Description of the Drawings of Figure 3, Pfam analysis of human EST AA315020 (SEQ ID NO:4) is cited. In the drawing of Figure 3, human EST AA315020 is cited but not SEQ ID NO:4. Instead, an amino acid sequence is depicted with the sequence identifier SEQ ID NO:38.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: In Figure 3, SEQ ID NO:38 is not mentioned in the description. In Figure 4A, the bottom panel of proteins are not mentioned in the description. In Figure 7, SEQ ID NO:37 is not mentioned in the description.

A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement

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sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance. No new matter may be added.

### ***Claim Objections***

Claim 19 is objected to because the instant claim encompasses non-elected inventions and require amendment to limit to elected invention. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.



Claim 19 (as it applies to SEQ ID NO:6) is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility.

The specification asserts that the invention is based in part upon the discovery of a nucleic acid sequence encoding a novel member of the Wnt signaling pathway. The novel member (FCTR<sub>X</sub>) encodes a *S100 cytokine-like polypeptide*. The specification teaches that S100 cytokine polypeptides are calcium-binding molecules with cytokine and chemokine activity. The specification teaches the nucleotide sequence of SEQ ID NO:5 and the ORF that encodes the translation product as SEQ ID NO:6 (page 8, lines 12-24). The specification asserts that the human sequence SEQ ID NO:6 has high similarity with the S100 family of proteins chemotactic cytokine II CCII polypeptide and Macrophage Migration Inhibition Factor (page 8, lines 29-34 and Figure 1). The specification states that the instant invention has high homology to previously described S100/IcaBP-type calcium binding domains (page 9, lines 9-33). The specification implies that serum concentrations of S100 cytokines according to the invention can be used as a marker for the clinical predictive value for metastatic tumors because the mouse gene fragment was originally identified in the tumors of Wnt-1 transgenic mice and human fragments used to produce the sequence were isolated from tumors (page 10, lines 7-20).

Generally, the art acknowledges that function cannot be predicted based solely on structural similarity to a protein found in the sequence databases. Skolnick *et al.* (2000, Trends in Biotech. 18:34-39) state that knowing the protein structure by itself is

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insufficient to annotate a number of functional classes, and is also insufficient for annotating the specific details of protein function (see Box 2, p. 36). The assertion that the instant invention has biological activities similar to known S100 proteins cannot be accepted in the absence of supporting evidence, because the relevant literature reports examples of polypeptide families wherein individual members have distinct, and sometimes even opposite, biological activities. For example, Yan *et al.* (Science 2000) establishes that a change in two amino acids in an epithelial morphogen regulates binding to two distinct receptors. This is even apparent in the instant specification. The instant invention is asserted as being a tumor marker. However, AY007220 which has homology with the instant invention (specification, Figure 4C) appears to be *downregulated* in lung carcinoma cells (Pietas *et al.*, reference submitted by Applicant).

Applicant cites Kligman *et al.* who teach that S100 proteins exert their biological effects probably by binding to and modulating effector proteins and all of the proteins have two EF hands per monomer. The specification does not state if these domains are in the instant protein. In addition, Kligman *et al.* disclose functional characteristics of different S100 proteins such as neurite extension, prolactin secretion, calcium-dependent microtubule dissociation, inhibition of phosphorylation. Some S100 proteins are associated with cell cycle expression or differentiation. The specification also lists a number of intracellular activities for S100, but none of these activities were demonstrated with the instant invention. Applicant cites Nacken *et al.*, who demonstrate that S100A9 protein is functionally equivalent to its human counterpart despite its low degree of sequence homology. However, in Nacken *et al.*, cell fractionation

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experiments, binding assays and expression experiments in specific cell line were employed to prove functionally equivalents, unlike in the instant specification.

As was stated above, the specification asserts the instant invention can be used as a marker for the clinical predictive value for metastatic tumors. Applicant cites various papers that link S100 proteins with malignancy. For instance, Djukanovic *et al.* (reference submitted by Applicant) report that S100B is expressed in melanoma tumor cells and is found in the sera of melanoma patients. In metastatic disease, S100B was frequently detected in patients sera and changes correlated with response or non-responsiveness to therapy. In the study, S100B from serum samples of melanoma patients and healthy donors were analyzed according to the internationally established cut-off levels. Donato (reference submitted by Applicant) reports that individual S100 proteins might have specific functional roles in the cell types where they are expressed. Because of their non-ubiquity and their up-regulation in specific tumor cells several S100 proteins are being used in diagnostic pathology. The paper of Donato also reveals how certain proteins were determined to have a role in metastatic phenotypes. For instance, expression of antisense RNA to S100A4 gene in high-metastatic A11 cells suppresses cell motility and *in vitro* invasiveness. Possible mechanisms of S100A4 include regulation of cell motility. A positive correlation has been found between hyperactivation of the Ndr kinase and overexpression of S100B in melanomas. Unlike the instant specification, the submitted references set parameters, document guidelines and employ proper experiments to identify potential mechanisms and functions of S100 proteins.

The specification states that the human gene sequence of the instant invention is highly expressed in several tumor cell lines, especially in colon cancer, breast cancer and ovarian cancer. The specification proposes that the instant invention has a role in cell proliferation and potential as a blood marker to identify and/or stage tumors. The specification proposes that expression or activity (tumor cell growth, cell migration and/or invasion) of the instant invention could be inhibited. This is not found persuasive because the specification does not teach functional characteristics/mechanisms of action of FCTR<sub>X</sub>. Therefore, it is unclear how FCTR<sub>X</sub> can be inhibited. Indeed, the utility of a claimed DNA does not necessarily depend on the function of the encoded gene product. Not all of the S100 proteins have a known mechanism. The instant invention would have a specific and substantial utility if the DNA hybridizes near a disease-associated gene or it has a gene regulating activity. The specification fails to disclose that the DNA of the instant application can be linked to a specific disease or gene regulating activity. There is no correlation to the predisposition of a particular disease and the claimed invention.

In the instant examples, several tumor cell lines appeared to have high expression of FCTR<sub>X</sub> while other tumor cell lines of the same tissue had low levels. There also appears to be high levels of expression in the normal adjacent tissue (NAT). There are problems with the tumor marker data disclosed in the instant specification. The tumor cell lines employed are not equal to tumor tissue. The cell culturing process alters gene expression and selects subgroups of cells, such that the cultured cells are not longer representative of the diseased tissue. The tumor cell lines were analyzed by

polymerase chain reaction (PCR). Insignificant expression levels are amplified until they appear significant. In addition, it is not apparent if there is control tissue for every tumor cell line. It is well known in the art that breast, colon and ovarian cancers have very different etiologies. The specification establishes no connection between any of these diverse cancers and FCTR<sub>X</sub>. The requirement of claim 37 is that the gene is linked to the presence of or predisposition to a disease. The specification does not disclose a clear nexus between any specific disease state and an alteration in level or form of the gene/protein. The specification fails to employ any of the parameters used in the papers cited above to determine that the invention could be used as a marker. Further experimentation is required before this asserted utility is substantial.

The specification asserts other utilities, which are neither specific and/or substantial. For instance, a process to screen for receptor agonists and/or antagonists, using probes to isolate other cDNAs with high sequence similarity, and making antibodies are not specific utilities. Agonist/antagonist assays are performed for any receptor-ligand pair when the physiological role of each is unknown. Antibodies can be made to any protein. A probe is a general utility that would be applicable to the broad class of the invention. A specific utility is a utility that is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. Furthermore, a specific utility amounts to more than a starting point for further research and investigation. It does not require or constitute carrying out further research to identify or reasonably confirm what the practical use might ultimately be.

The instant application has failed to provide guidance as to how one of skill in the art could use the claimed invention in a way that constitutes a specific or substantial utility. The proposed uses of the claimed invention are simply starting points for further research and investigation into potential practical uses of the claimed invention.

Claim 19 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

In addition, the specification does not reasonably provide enablement for SEQ ID NO:6 or nucleic acid sequences encoding variants of SEQ ID NO:3 and SEQ ID NO:6.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Since the claimed invention (SEQ ID NO:6) is not supported by either a credible, specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. In addition, the instant claims are not enabled for nucleic acid sequences encoding variants/mutations of SEQ ID NO:3 and SEQ ID NO:6.

There is no guidance in the specification or working examples showing what variant sequence is overexpressed in the specific tumors. If one skilled in the art were to make probes from the claimed variants, there is no guidance (or working examples)

regarding what changes can be made without loss of probe specificity. The specification fails to teach how to make nucleic acid sequences that would encode variant polypeptides of SEQ ID NO:3 and SEQ ID NO:6, which could be used in cancer treatment (antagonist or agonist). As is well recognized in the art, any modification (even a "conservative" substitution) to a critical structural region of a protein is likely to significantly alter its functional properties. It is known for nucleic acids as well as proteins, that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many cases (see Wells, 1990, Biochemistry 29:8509-8517). There is no guidance in the specification or working examples regarding what changes that can be made in the encoding sequence without loss of activity of the polypeptide.

The claims encompass an unreasonable number of inoperative nucleic acids, which the skilled artisan would not know how to use. The specification does not teach how to make any variant of the exemplified sequence and provides no assay to evaluate the function. There are no working examples of nucleic acid sequences less than 100% identical to nucleic acid sequences encoding SEQ ID NO:3 or SEQ ID NO:6, thus the skilled artisan would not know how to use non-identical sequences on the basis of the teachings in the specification unless they possessed some sort of function, which the specification fails to teach.

For these reasons, which include the complexity and unpredictability of the nature of the invention and art in terms of the lack of knowledge about function of nucleic acid sequences encoding SEQ ID NO:6 and nucleic acid sequences encoding

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variants of SEQ ID NO:3 and SEQ ID NO:6, the lack of working examples and the lack of direction or guidance regarding same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which recite structure without function, it would require undue experimentation to the use the invention.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification provides adequate written description for nucleic acids encoding SEQ ID NO:3 and SEQ ID NO:6, but not variants thereof. The instant claim is drawn to nucleic acids encoding variant forms of SEQ ID NO:3 and SEQ ID NO:6 and nucleic acids hybridizing to sequences **with no stringency conditions**.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116).



With the exception of SEQ ID NO:3 and SEQ ID NO:6 the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides and polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Furthermore, in the absence of a recitation of clear hybridization conditions, the nucleic acid probe will hybridize with unrelated DNA sequences, corresponding sequences from other species, mutated sequences, allelic variants, splice variants and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated sequences set forth in SEQ ID NO:3 and SEQ ID NO:6, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 is indefinite in the recitation of a polynucleotide sequence in the absence of a referenced SEQ ID NO: The metes and bounds of the instant claim cannot be determined.

Claims 19 and 38 are drawn to methods for determining the presence of a nucleic acid in a sample. The methods would require the use of hybridization conditions, which are missing from the instant claims. In the absence of a recitation of clear hybridization conditions (e.g., "hybridizes at wash conditions of A X SSC and B % SDS at CoC"), the claims fail to define the metes and bounds of the varying structures of polynucleotides recited in the claimed methods. Stringency is relative, and the art does not recognize a single set of conditions as stringent. The specification does not provide an unambiguous definition for the term.

***Conclusion***

No claims are allowed.

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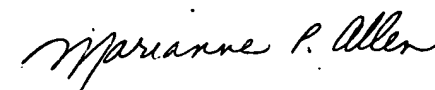
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



RMD  
7/25/06



MARIANNE P. ALLEN  
PRIMARY EXAMINER  
7/27/06  
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